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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,129	06/25/2001	Ryuji Ueno	210227US0XPC	2213

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EXAMINER

CHISM, BILLY D

ART UNIT PAPER NUMBER

1654

DATE MAILED: 05/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/869,129

Applicant(s)

UENO, RYUJI

Examiner

B. Dell Chism

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9 and 11-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9 and 11-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/23/03: 01/09/04
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Withdrawal of Objections and Rejections

The rejections and/or objections made in the final office action dated 24 September 2003, which are not explicitly stated below, in original or modified form are withdrawn. Applicants' arguments filed in the now entered After Final, dated 23 December 2003 and as requested for entry in the present Request for Continued Examination, will be addressed to the extent that they pertain to the present grounds of rejection.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 9 and 11-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishioka *et al.* (cited in previous office action) in combination with Stuchlik *et al.* (WO 99/34830) (cited in previous office action) and Nussenblatt R.B. (Int. Rev. Immunol. 1997, Vol. 14, No. 1, pages 67-79).

Ishioka *et al.* teaches the use of immunosuppressive agents, i.e., FK506, of the claimed structures in treating inflammation of inner ocular tissues (uveitis), however, Ishioka *et al.* does not teach local application to the eye.

Stuchlik *et al.* teaches use of immunosuppressants (macrolide lactones, i.e., tacrolimus (FK506)) for local topical treatment to the eye as well as various types of carriers and/or delivery compounds for such use, wherein Stuchlik *et al.* teach methods of increasing penetration of such compounds across the cornea, via topical application, into the internal tissues of the eye (page 4). Stuchlik *et al.* also teach applicability of the topicals in preparations as “characterized by high penetration of immunosuppressive agents into ocular tissues and in a very good tolerability.”

Although Stuchlik *et al.* does not teach a method of using a composition comprising the specifically claimed concentration of the compounds for the local administration, absent some evidence to the contrary, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have optimized the concentration for local administration. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235.

Nussenblatt teaches the use of tacrolimus and other macrolides for treatment in Behcet's syndrome, wherein Nussenblatt points out that Behcet's syndrome is usually accompanied by retinal vessel occlusive disease, and that complications of the inflammation can include retinal atrophy and retinal detachment. The present claims indicate that retinal artery occlusion, which is an ischaemic retinopathy, which is retinopathy, is treatable with a local administration of a composition comprising a macrolide of formula I. Nussenblatt discloses treating these situations with tacrolimus for reducing the inflammation.

Furthermore, it would be obvious to one of skill in the art that the penetration of a macrolide lactones, i.e., tacrolimus, into the internal tissues, as disclosed by Stuchlik *et al.*, of the

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eye would encompass the retina and the tissues associated. Thus, Stuchlik *et al.* renders obvious the method of applying the presently claimed compound locally to the eye for treatment of situation comprising inflammation disorders of ocular tissues, i.e., Behcet's syndrome, uveitis, and retinopathy, which is damage to the internal tissues of the eye as is described in Stuchlik *et al.*, Nussenblatt and Ishioka *et al.*

Thus, absent evidence to the contrary, together these three prior art references render the presently claimed methods *prima facie* obvious, wherein one of ordinary skill in the art at the time of the present invention would have motivated to optimize dosages and concentrations, and delivery techniques using methods known in the art.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claim 22 is rejected under 35 U.S.C. 102(a) as being anticipated by Stuchlik *et al.* (WO 99/34830) (cited in previous office action). Stuchlik *et al.* teaches the claimed compound (i.e., tacrolimus and other macrolides) for local treatment of the eye. These compounds are in solutions buffered for administration to the eye, as well as other possible additives (page 7-8).

Conclusion

6. No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 571-272-0962. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

B. Dell Chism



CHRISTOPHER R. TATE
PRIMARY EXAMINER